

Application No. 10/611,414
Office Action Dated September 6, 2006
Amendment Dated February 6, 2007

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REMARKS

Claims 22-83 have been withdrawn from consideration. This Amendment cancels claim 18, without prejudice or disclaimer, and adds new claims 84 and 85. Thus, claims 1-17, 19-21, 84, and 85 are pending. No new matter is added. Reconsideration and prompt favorable action are respectfully requested.

Rejection of Claims 1-21 under 35 U.S.C. §112

At page 2, the Office Action dated September 6, 2006, rejected claims 1-21 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicants regard as the invention. The Office Action indicated that the phrase "each cluster associated with a discrete allelic combination" in claim 1 is indefinite. Applicants respectfully submit that the term "discrete allelic combination" in claim 1 is adequately clear. To advance the progress of the application Applicants have, however, amended claim 1 to recite features that each data cluster is "associated with a discrete combination selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele." The rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action indicated that the phrase "applying the likelihood model to each of the plurality of samples to determine its associated allelic composition" in claim 1 is indefinite, due to the presence of the term "its." Applicants respectfully submit that the phrase "applying the likelihood model to each of the plurality of samples to determine its associated allelic

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composition" is adequately clear. To advance the progress of the application Applicants have, however, amended claim 1 to recite features of "applying the likelihood model to each of the plurality of samples to determine an associated allelic classification for each corresponding sample of the plurality of samples." The rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action indicated that claim 1 is indefinite due to the recited features of determining an "allelic composition," due to inconsistency with the phrase in the preamble "allelic classification." Applicants respectfully submit that no indefiniteness in the scope of the claim resulted from the phrase "allelic composition." To advance the progress of the application Applicants have, however, amended claim 1 to consistently recite "allelic classification." The rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action indicated that claim 5 is indefinite due to the phrase "wherein the data clusters comprise at least three discrete clusters." Applicants respectfully submit that the scope of claim 5 is adequately clear. To advance the progress of the application Applicants have, however, amended claim 5 to recite features that the "one or more data clusters comprise at least three discrete data clusters each associated with a different combination," and therefore make claim 5 even more definite. The rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action rejected claims 6 and 7, which depend from claim 5, due to the phrase "data clusters." Claims 6 and 7 have been similarly amended to refer to the "at least three

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discrete data clusters,” consistent with claim 5. The rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action rejected claim 13 due to the phrase “no template control” sample. Applicants respectfully submit that the term “no template control” sample is adequately clear, including because that phrase is described, for example, at page 12, paragraph [0040], of Applicants’ specification. To advance the progress of the application Applicants have, however, amended claim 13 to recite features of a “control sample.” The rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested. The rejection of claims 1-17 and 19-21 under 35 U.S.C. §112, second paragraph, is overcome. Reconsideration and withdrawal of the rejection of the claims on these grounds is respectfully requested.

Rejection of Claims 1-21 under 35 U.S.C. §101

At page 4, the Office Action rejected claims 1-21 under 35 U.S.C. §101 on the grounds that the claimed invention is directed to non-statutory subject matter. The Office Action indicated that claim 1 and dependent claims 2-21 lack a “concrete, tangible and useful result” and therefore are not entitled to patent protection.

Applicants respectfully submit that features of claim 1 including “applying the likelihood model to each of the plurality of samples to determine an associated allelic composition” are entirely concrete, tangible and useful for a variety of applications that utilize or depend on determining alleles, including various genetic studies and/or epidemiology, for example. Applicants respectfully submit that further features of claim 1 including “outputting the allelic

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classification of each of the plurality of samples" even further demonstrate the concrete, tangible and useful nature of the claimed invention. The rejection of claims 1-17 and 19-21 under 35 U.S.C. §101 is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 5-9, 10-11, 16 and 18 under 35 U.S.C. §102

At page 5, the Office Action rejected claims 1, 5-9, 10-11, 16, and 18 under 35 U.S.C. §102(e) as being anticipated by Landers et al. (U.S. Patent No. 6,703,228). Claim 1 recites a method for allelic classification, including features of "acquiring intensity information for a plurality of samples wherein the intensity information comprises a first intensity component representing the detected emission of a first probe associated with a first allele and a second intensity component representing the detected emission of a second probe associated with a second allele." As part of the recited method for allelic classification, claim 1 also includes features of "evaluating at least the relationship between the first intensity component and the second intensity component for each of the plurality of samples to identify one or more data clusters, each data cluster associated with a discrete combination selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele." Claim 1 further includes features of "generating a likelihood model that predicts the probability that a selected sample from the plurality of samples will reside within a particular data cluster of the one or more data clusters based upon the intensity information of the selected sample."

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Landers et al. fails to identically describe a method for allelic classification as claimed in claim 1, including features of "evaluating at least the relationship between the first intensity component and the second intensity component for each of the plurality of samples to identify one or more data clusters, each data cluster associated with a discrete combination" of first and second alleles. Landers et al. fails to disclose or suggest the discrimination of data clusters based on the relationship of intensity components representing "detected emissions" of first and second probes, each cluster being associated with different combination of alleles, at all.

Landers et al. describes, for example at columns 31-32, the identification of the frequency of various SNP markers at the level of a population to determine genetic linkages to various diseases, but not the accurate determination of SNP classifications, themselves. That is, the teachings of Landers et al. presume the ability to isolate underlying single nucleotide polymorphisms (SNPs) without any explanation or consideration of how allelic classification would actually take place, and Landers et al. certainly fails to describe all features of claim 1. Landers et al. further fails to describe, for example and among other features, "generating a likelihood model that predicts the probability that a selected sample from the plurality of samples will reside within a particular data cluster of the one or more data clusters based upon the intensity information of the selected sample." Landers et al. does not describe, suggest, or even contemplate introducing a likelihood model that predicts the probability of a sample residing within a particular cluster, based upon intensity information representing component probe emissions, nor applying any likelihood model before allelic classification of each takes place, in the first place. The rejection of claim 1 under 35 U.S. 102(e) as being anticipated by Landers et

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al. is overcome. The rejection is respectfully traversed. Reconsideration is respectfully requested.

Claims 5-9, 10-11, and 16 distinguish over Landers et al. for at least the same reasons as claim 1, from which they depend, does. Claim 18 is canceled. The rejection of claims 5-9, 10-11, and 16 under 35 U.S. 102(e) is overcome. The rejection is respectfully traversed. Reconsideration is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

Should the Examiner deem that any further action by Applicants or Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

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If there are any other fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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